# TPPs' alleged spread knowledge acquired by virtue of purchases of self-administered drugs

# UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY	)	
AVERAGE WHOLESALE PRICE	.)	MDL No. 1456
LITIGATION	)	Civil Action No. 01-12257-PBS
	)	
	)	Judge Patti B. Saris
	)	
THIS DOCUMENT RELATES TO	)	[FILED UNDER SEAL
01-CV-12257-PBS AND 01-CV-339	)	PURSUANT TO COURT ORDER]

DECLARATION OF ERIC M. GAIER, PH.D., IN SUPPORT OF TRACK 1 DEFENDANTS' JOINT MOTION FOR SUMMARY JUDGMENT

March 15, 2006

# IV. Drug purchases made by TPPs

(4) As I discussed in my previous declarations, knowledge regarding the differences between AWP and provider acquisition costs, as a matter of economic theory, would prevent payors from overpaying for prescription drugs as a result of the alleged AWP scheme and therefore insulate them from economic harm. As plaintiffs' expert Dr. Hartman states:

Had the existence of the 'mega-spreads' been perceived and understood by TPPs, those payors would have negotiated more aggressively than they did, leading to lower reimbursement rates.<sup>4</sup>

Judge Saris also recognizes the importance of knowledge and sophistication of TPPs. Specifically, she states:

Some TPPs may have greater sophistication because they purchase selfadministered drugs, but there is no evidence that TPPs purchase physicianadministered drugs or know of the mega-spreads that exist for these drugs.<sup>5</sup>

It is therefore appropriate to focus on the question of what TPPs in Massachusetts knew about the differences between AWP and provider acquisition costs, and in particular on whether they would have gained knowledge through purchases of physician-administered drugs. The evidence demonstrates that TPPs covering approximately 70 percent of beneficiaries in Massachusetts bought physician-administered drugs throughout the class period. Through those purchases Massachusetts TPPs knew of the widely varying differences between AWP and provider acquisition costs, generally knew the magnitude of these differences, and were aware of those differences since at least 1991 (the earliest date covered by data provided by defendants).

Gaier Declaration, Section IV.4. Also see Sur-Reply Declaration of Eric M. Gaier, Ph.D. in Support of Defendants' Opposition to Class Certification, U. S. District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257-PBS, October 25, 2004, ("Gaier Sur-Reply Declaration"), Section V.

Hartman Liability and Damages Declaration, p. 10.

Memorandum and Order Re: Motion for Class Certification, U. S. District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257, August 16, 2005, ("Saris' Class Certification Order"), p.59.

(5) The provision of health insurance in Massachusetts is relatively concentrated, with approximately 86 percent of the covered lives insured by five TPPs. Indeed, named plaintiff and class representative Blue Cross and Blue Shield of Massachusetts ("BCBS-MA") is the largest TPP in Massachusetts, insuring approximately 46 percent of the covered lives in 2004. BCBS-MA also offers Medicare Supplemental Insurance ("Medigap") plans to beneficiaries in Massachusetts. It is instructive to also examine other large plans in Massachusetts; Table 1 summarizes the covered lives for the largest TPPs in Massachusetts.

Table 1: Massachusetts health plans by number of enrollees

Health plan	Total enrollees (1,000s)	Share of covered lives
Blue Cross Blue Shield of Massachusetts	2,288	46%
-Tufts Associated Health Plan ("Tufts")	803	16%
Harvard Pilgrim Health Care, Inc. ("Harvard Pilgrim")	766	15%
CIGNA HealthCare of Massachusetts, Inc. ("CIGNA")	229	5%
Fallon Community Health Plan ("Fallon")	187	4%
Other (10 plans with more than 1,000 enrolled)	695	14%
Total	4,969	100%

Sources: AIS database, 2004.

(6) Sales data provided by defendants demonstrate that four of the top five Massachusetts TPPs—plaintiff BCBS-MA, Harvard Pilgrim, CIGNA, and Fallon—purchased physician-administered drugs directly through contracts with manufacturers, through group purchasing organizations ("GPO"s), or through drug wholesalers. These purchases were made by organizations that provided medical care, required a supply of drugs for their operation, and were owned by these TPPs. For example, Harvard Pilgrim and Fallon were staff/group-model HMOs, which are vertically integrated entities that provide both health care and insurance services. Although this form of integrated health plan arrangement is less prevalent

http://www.mass.gov/doi/Consumer/HealthLists/medicare\_2006.PDF

See Appendix C for documentation of entities operated by these Massachusetts TPPs for which manufacturers document sales of physician-administered drugs.

today, many insurers owned, or operated such entities during the 1990s and would have purchased physician-administered drugs.<sup>8</sup>

(7) The available evidence from manufacturers shows that these TPPs purchased significant volumes of physician-administered drugs, including many of the drugs in this litigation. Table 2 lists dollar volumes of subject physician-administered drugs purchased by these payors, by manufacturer. In addition, those TPP drug purchases were made over an extended period-spanning the entire class period-and starting at least as early as 1991 (the earliest time period for which data have been provided by defendants). Table 3 lists dollar volumes of subject physician-administered drugs purchased by these TPPs over time.

See Kongstvedt, Peter R. The Managed Care Handbook, Aspen Publishers, Gaithersburg, 2001, pp. 34-36 for a description of this type of organization.

Table 2: Dollar volumes of subject drugs purchased directly by Massachusetts TPPs, by manufacturer

Manufacturer	Time coverage of available data	BCBS-MA°	CIGNA <sup>10</sup>	Fallon <sup>11</sup>	Harvard Pilgrim <sup>12</sup>
AstraZeneca	91-04	<u> </u>	\$1,725,836	\$1,275,699	\$1,231,925
Bristol-Myers Squibb	93-02	\$138,389	\$1,099,332	\$942,688	\$706,249
GlaxoSmithKline	97–01	\$195,951	\$3,933,904	\$875,213	\$1,371,627
Johnson & Johnson	91–99	\$511,377	\$3,595,116	\$1,077,477	\$1,172,335
Schering-Plough	91–04	\$96,549	\$5,178,432	\$2,591,897	\$2,048,990
	Total	\$942,265	\$15,532,620	\$6,762,975	\$6,531,127

Source: AstraZeneca, Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, and Schering-Plough Indirect sales data.

I include all purchases in which plaintiff BCBS-MA or its related entities are listed as customers or contract owners in manufacturer chargeback data. Plaintiff BCBS-MA-related entities purchasing subject drugs directly from manufacturers include HMO Blue, Medical East, and Medical West.

I include all purchases in which CIGNA or its related entities are listed as customers or contract owners in manufacturer chargeback data. CIGNA-related entities purchasing subject drugs directly from the manufacturers include CIGNA Healthplan, CIGNA Pharmacy, Connecticut General Life Insurance Company, INA Healthplan, Lovelace, Tel-Drug, EQUICOR, and Healthsource.

I include all purchases in which Fallon or its related entities are listed as customers or contract owners in manufacturer chargeback data. Fallon-related entities purchasing subject drugs directly from manufacturers include Fallon Community Health Care, Fallon Clinic, and Fallon Central Pharmacy.

<sup>&</sup>lt;sup>12</sup> I include all purchases in which Harvard Pilgrim or its related entities are listed as customers or contract owners in manufacturer chargeback data. Harvard Pilgrim-related entities purchasing subject drugs directly from manufacturers include Harvard Pilgrim Healthcare, Harvard Community Health Plan, Harvard Vanguard, and Rhode Island Group Health (also known as Harvard Community Health Plan of New England).

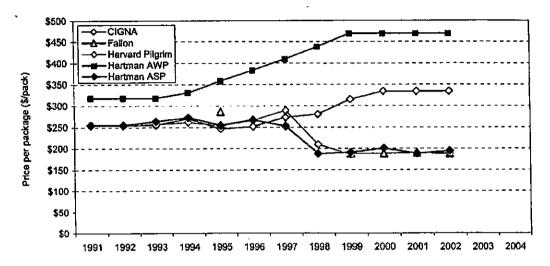
Table 3: Dollar volumes of subject drugs purchased directly by Massachusetts TPPs, by year

Year	BCBS-MA	CIGNA	Fallon	Harvard Pilgrim
1991	\$873	\$333,323	\$36,258	\$79,334
1992	\$24,757	\$676,409	\$60,983	\$153,853
1993	\$56,739	\$969,456	\$182,672	\$224,164
1994	\$97,608	\$1,252,642	\$296,381	\$349,408
1995	\$123,943	\$1,525,829	\$187,848	\$514,739
1996	\$204,843	\$1,549,650	\$426,002	\$908,120
1997	\$275,633	\$1,739,627	\$785,632	\$1,331,506
1998	\$104,916	\$2,218,061	\$1,100,364	\$1,142,811
1999	\$27,136	\$1,850,194	\$1,185,501	\$870,944
2000	\$20,829	\$1,444,482	\$949,111	\$371,965
2001	\$4,989	\$1,191,893	\$959,915	\$379,568
2002		\$583,350	\$539,284	\$142,822
2003		\$154,352	\$45,639	\$47,424
2004		\$43,352	\$7,385	\$14,469
Total	\$942,265	\$15,532,620	\$6,762,975	\$6,531,127

Source: AstraZeneca, Bristof-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, and Schering-Plough indirect sales data.

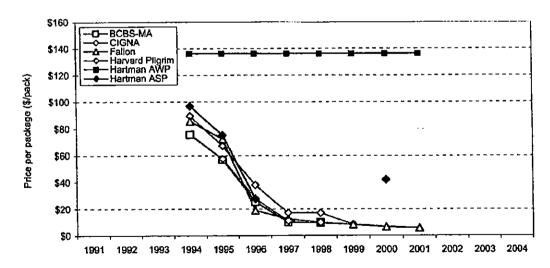
(8) Importantly, these Massachusetts TPPs purchased physician-administered drugs at discounted prices generally at, and in many cases below, the ASPs calculated by plaintiffs' expert Dr. Hartman. Therefore, these TPPs would have known about the widely varying differences between AWP and provider acquisition costs and would have known about the magnitude of these differences for the very drugs for which Dr. Hartman purports to find damages. Figure 1 to Figure 5 below depict the AWP and ASP reported by Dr. Hartman along with the average discounted prices paid by the Massachusetts TPPs for a sample of the physician-administered drugs for which Dr. Hartman finds damages. Appendix B contains corresponding figures for additional subject drugs purchased by Massachusetts TPPs.

Figure 1: Zoladex prices to Massachusetts TPPs



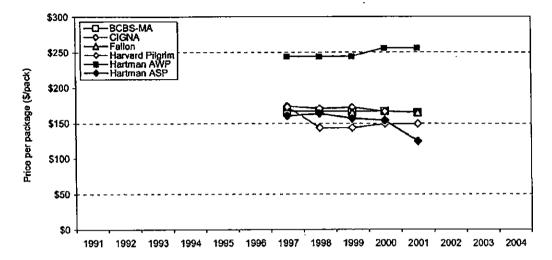
Source: AstraZeneca indirect sales table—NDC 00310096036

Figure 2: Vepesid prices to Massachusetts TPPs



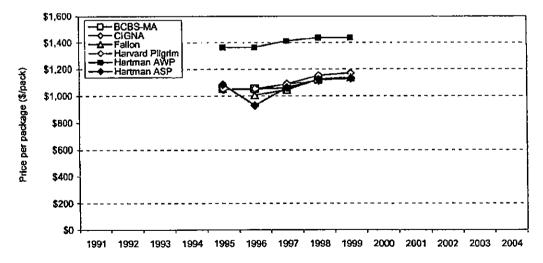
Source: Bristol-Myers Squibb Indirect sales data—NDC 00015309520

Figure 3: Zofran prices to Massachusetts TPPs



Source: GlaxoSmithKline indirect sales tables—NDC 00173044200

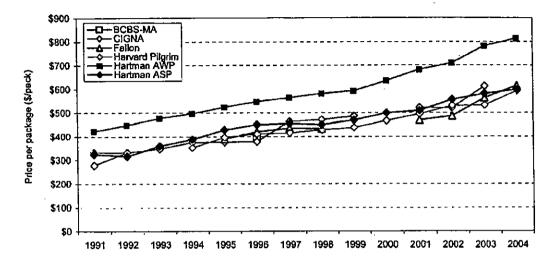
Figure 4: Procrit prices to Massachusetts TPPs



Source: Johnson & Johnson Indirect sales table--- NDC 59876031201

CANADA CONTRACTOR CONT

Figure 5: Intron prices to Massachusetts TPPs



Source: Schering-Plough Indirect sales lables-NDC 00085053901

(9) The manufacturers' sales data demonstrate that at least four of the largest five TPPs in Massachusetts—including plaintiff BCBS-MA and collectively representing approximately 70 percent of the beneficiaries in Massachusetts—had knowledge that the subject physician-administered drugs were available to providers at substantial discounts from AWP and knew the magnitude of those discounts since at least 1991. This is the very information that Dr. Hartman concedes would have caused payors to have "negotiated more aggressively than they did, leading to lower reimbursement rates." 13

<sup>13</sup> Hartman Liability and Damages Declaration, p. 10.

Declaration of Eric M. Gaier, Ph.D.	
	·
I declare under penalty of perjury that this declaration	on is true and correct.
< 4	March 15, 2006
Eric M. Gaier, Ph.D.	
Elic M. Calci, i ii.D.	Date
Elic M. Galci, I h.D.	Date
Elle M. Galet, Fli.D.	Date .
Elle M. Galet, I h.D.	Date .
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# **Appendix A: Materials considered**

#### **Declarations**

- Declaration of Eric M. Gaier, Ph.D. in Support of Defendants' Opposition to Class Certification, U. S. District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257-PBS, October 25, 2004
- Declaration of Raymond S. Hartman In Support of Plaintiffs' Claims of Liability and Calculation of Damages, U. S. District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257-PBS, December 15, 2005
- Liability Report of Dr. Meredith Rosenthal, December 15, 2005.
- Memorandum and Order Re: Motion for Class Certification, U. S. District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257, August 16, 2005
- Sur-Reply Declaration of Eric M. Gaier, Ph.D. in Support of Defendants' Opposition to Class Certification, U. S. District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257-PBS, October 25, 2004

## **Depositions**

· Mulrey, Michael: Blue Cross Blue Shield of Massachusetts

#### Electronic data

- AstraZeneca Chargeback Data
  - cntmgt pulmicortresp\_indirect\_sales
  - cntmgt\_zoladex\_indirect\_sales
  - AZ\_Sales\_Based\_Customers.csv
- Bristol-Myers Squibb Chargeback Data

- bms\_indirect\_pre1997
- GlaxoSmithKline Chargeback Data
  - cn\_sales\_v
  - tcbline
- Johnson & Johnson Chargeback Data
  - jj\_imhc\_combined\_chargeback
- Schering-Plough Chargeback Data
  - schering\_chargeback\_1991\_1994
  - schering\_chargeback\_1995\_1998
  - schering\_chargeback\_1999\_2001
  - schering\_chargeback\_2002\_2004

# **Publicly available documents**

- AIS's Directory of Health Plans: 2004, MCOs table
- Kongstvedt, Peter R. The Managed Care Handbook, Aspen Publishers, Gaithersburg, 2001

#### Websites

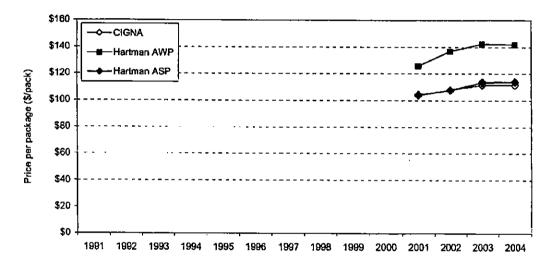
- http://www.bluecrossma.com/common/en\_US/aboutUsIndex.jsp
- http://www.bluecrossma.com/common/en\_US/healthPlansIndex.jsp?levelOneDotFive
   Category=HMO&levelTwoCategory=HMO+Blue&targetTemplate=titleBodyAddLvl.jsp
- http://www.bluecrossma.com/common/en\_US/aboutUsIndex.jsp?repId=
  Repositories.PressReleases.2001PressReleases.pressRelease04052001.xml&levelTwoCat
  egory=News+%28with+Archives%29&isLevelThreeSelected=true&targetTemplate=pres
  sReleaseDetail.jsp&iphl=medicall:medical:east

- http://caselaw.lp.findlaw.com/cgi-bin/getcase.pl?court=1st&navby=case&no=012586
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstr act&list\_uids=10133054&query\_hl=2&itool=pubmed\_docsum
- http://www.cigna.com/health/consumer/service/pharmacy\_claim.html
- http://www.cigna.com/general/about/history.html
- http://www.cigna.com/general/about/investor/release/10k20021231.html
- http://www.ardenthealth.com/CustomPage.asp?PageName=Lovelace
- http://www.lovelacesandia.com/CustomPage.asp?guidCustomContentID=A89B6170-7BC2-4F3D-97A5-41F9BA70E1D5
- http://www.equityleague.org/PDF/cigna\_pharmacy\_guide.pdf
- http://www.fchp.org/about/index.aspx
- http://www.fchp.org/brokers/qa.aspx#Anchor246
- http://www.bizjournals.com/boston/stories/2005/01/03/daily50.html
- http://www.fallonclinicfoundation.org/ourstory/ourstory.aspx
- http://www.fchp.org/SeniorPortal/Sales.aspx
- http://www.fallonclinic.com/internet/patients/index.aspx?PAGE=locations&LEVEL1=patients&LEVEL2=locations
- http://www.fchp.org/brokers/resources/brokerEdge/BrokerEdgeFall02.pdf
- http://www.prospect.org/columns/kuttner/bk000109.html
- http://www.bizjournals.com/boston/stories/1999/12/20/story6.html
- http://www.harvardvanguard.org/about/faq.asp
- http://www.managedcaremag.com/archives/0002/0002.harvard.html
- http://findarticles.com/p/articles/mi\_qa4100/is\_200506/ai\_n14715983

# Appendix B: Additional examples of drugs purchased by Massachusetts TPPs<sup>14</sup>

# AstraZeneca<sup>15</sup>

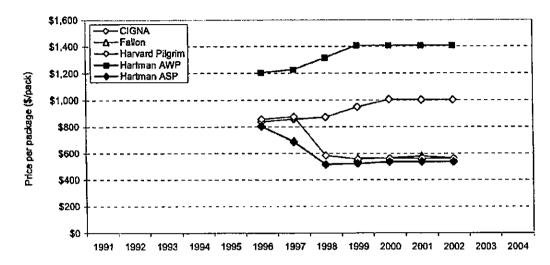
Figure 6: PULMICORT (NDC 00186198804)



See Appendix C for explanation of the calculation of dollars and prices to Massachusetts TPPs.

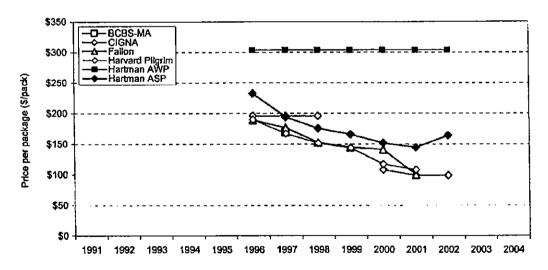
<sup>15</sup> Source: AstraZeneca indirect sales table.

Figure 7: ZOLADEX (NDC 00310096130)



# Bristol-Myers Squibb16

Figure 8: BLENOXANE (NDC 00015301020)



Source: Bristol-Myers Squibb indirect sales data.

Figure 9: CYTOXAN (NDC 00015050301)

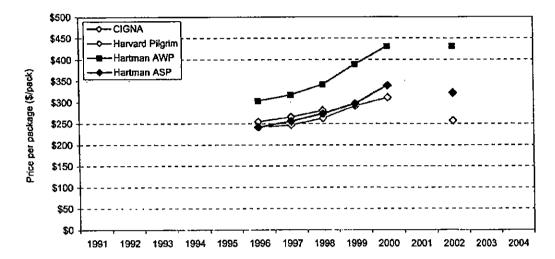


Figure 10: CYTOXAN (NDC 00015054841)

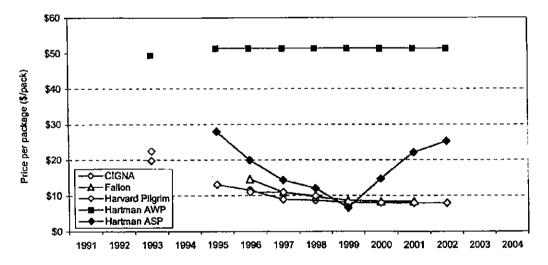


Figure 11: PARAPLATIN (NDC 00015321530)

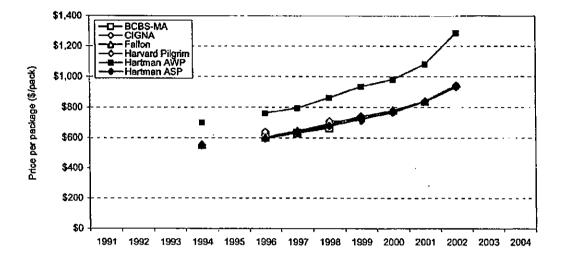
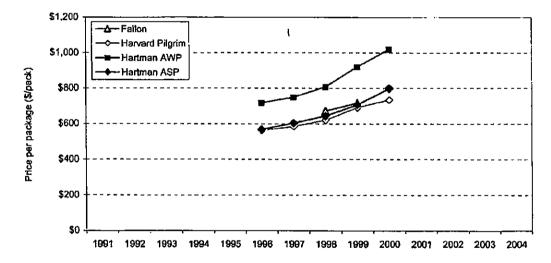


Figure 12: VEPESID (NDC 00015309145)



## GlaxoSmithKline<sup>17</sup>

Figure 13: KYTRIL (NDC 00029414901)

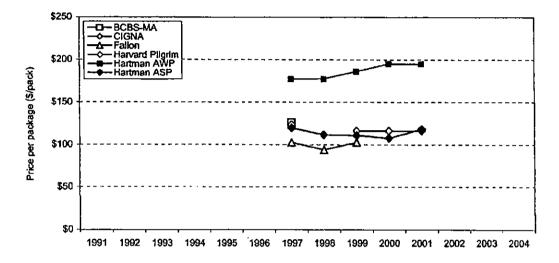
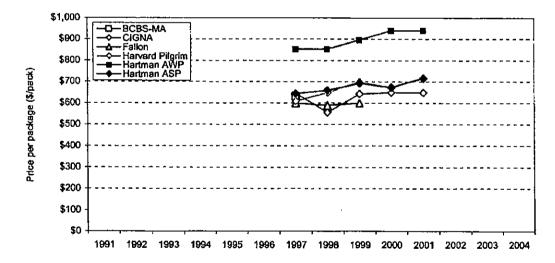
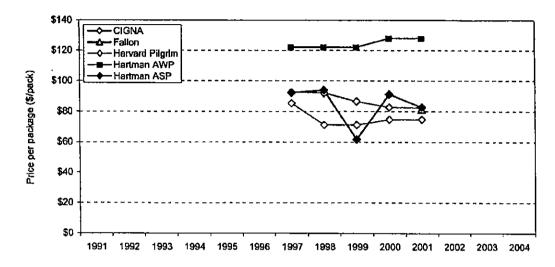


Figure 14: KYTRIL (NDC 00029415105)



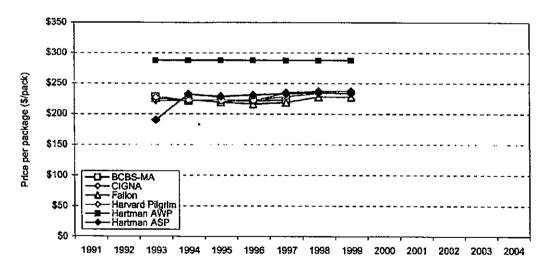
Source: GlaxoSmithKline indirect sales tables.

Figure 15: ZOFRAN (NDC 00173044202)



# Johnson & Johnson 18

Figure 16: PROCRIT (NDC 59676030401)



Source: Johnson & Johnson indirect sales table.

Figure 17: PROCRIT (NDC 59676031001)

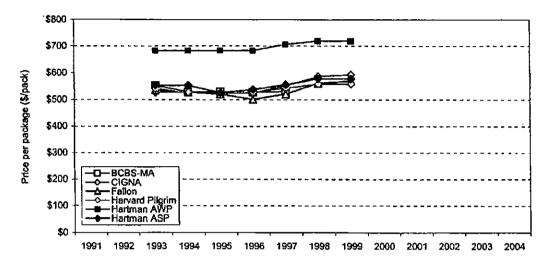
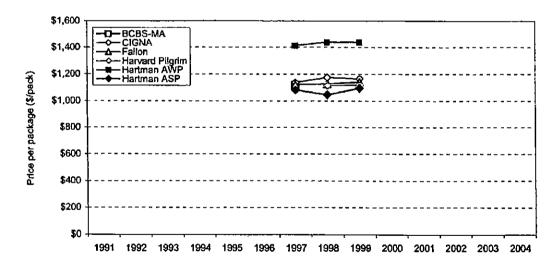


Figure 18: PROCRIT (NDC 59676032001)



# Schering-Plough<sup>19</sup>

Figure 19: ALBUTEROL (NDC 5993015008)

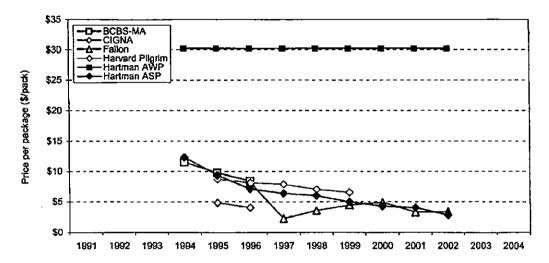
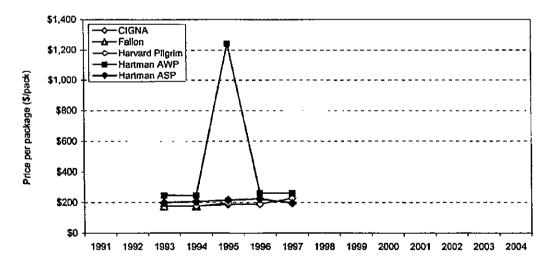


Figure 20: INTRON (NDC 00085076901)<sup>20</sup>



<sup>19</sup> Source: Schering-Plough indirect sales tables.

Dr. Hartman's AWP of \$1,244.40 in 1995 appears to be incorrect. From January 1, 1995 until March 1, 1995, the AWP published in Medi-Span is \$248.88. Effective March 1, 1995 and continuing through the end of the year, the AWP published in Medi-Span is \$262.57. See Medi-Span Comprehensive Price History File.

Figure 21: INTRON (NDC 00085118402)

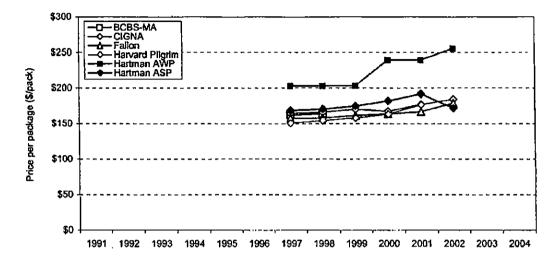


Figure 22: PERPHENAZINE (NDC 59930160501)

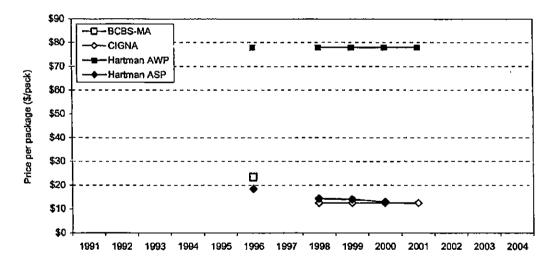


Figure 23: PROVENTIL (NDC 00085020802)

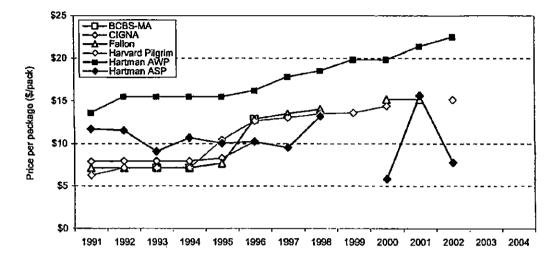
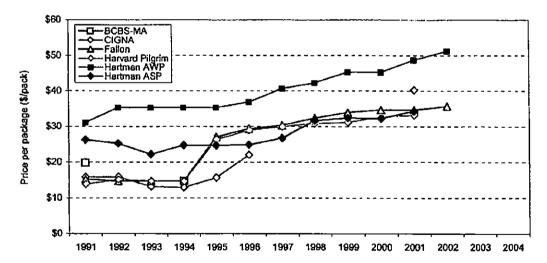


Figure 24: PROVENTIL (NDC 00085020901)



# Appendix C: Calculation of sales dollars and prices to Massachusetts TPPs

(10) In this appendix, I describe the electronic source data and data processing I employ to identify relevant Massachusetts TPP entities and calculate the dollar volumes and prices they paid for physician-administered drugs. I also list the relevant purchasing entities and detail their relationships with the Massachusetts TPPs.

#### Electronic source data

(11) I calculate dollar volumes and prices paid by Massachusetts TPPs using manufacturer chargeback sales data. Below, I list the data tables used for each manufacturer, along with the drugs and time periods for which data were available. I also list the fields used to calculate dollar volumes and prices and the fields used to identify relevant purchasing entities. These entities were identified using the combination of three types of fields: customer name, contract owner name, and state.

#### **AstraZeneca**

#### Data tables

- cntmgt\_pulmicortresp\_indirect\_sales
- cntmgt\_zoladex\_indirect\_sales
- AZ Sales Based Customers.csv—produced by Dr. Hartman on February 3, 2006

#### Drugs included

Pulmicort respules, Zoladex

#### Time coverage

• 1991-2004

Fields for calculating dollar volumes and prices

- net\_sales
- no\_of\_packages

Field for identifying relevant purchasing entities

- customer\_name
- contract\_owner
- state

Fields for identifying products

• product\_ndc

## **Bristol-Myers Squibb**

Data tables

Indirect.txt

Drugs included

• Blenoxane, Cytoxan, Paraplatin, Taxol, Vepesid

Time coverage

• 1993-2002

Fields for calculating dollar volumes and prices

- chbk-adj-contr-prc
- chbk-adj-prod-qty

Fields for identifying relevant purchasing entities

- custname
- ownername
- custst

Fields for identifying products

• chbk-ndc-prod-code

#### Glaxo\$mithKline

#### Data tables

- · Sales tables
  - cn\_sales\_v
  - tcbline
- · Purchaser translation tables
  - cn\_bu\_vl
  - trpcustmst

#### Drugs included

• Imitrex, Kytril, Navelbine, Ventolin, Zofran

#### Time coverage

• 1997-2001

Fields for calculating dollar volumes and prices

- contr\_sls\_amt
- cont\_prod\_prc
- pkg\_unit\_qty
- prod\_qty

Field for identifying relevant purchasing entities

- cust\_name
- bu\_nm
- hin\_name
- bu\_std\_nm

- owner\_cust\_name .
- cust\_state, dflt\_st\_cd

Fields for identifying products

- nwda\_ndcll\_no
- prod\_nmbr

#### Johnson & Johnson

#### Data tables

• jj\_imhc\_combined\_chargeback

#### Drugs included

• Procrit

#### Time coverage

• 1991-1999

Fields for calculating dollar volumes and prices

- amt\_contract\_price
- units

Fields for identifying relevant purchasing entities

- cust\_name
- cust\_state

Fields for identifying products

ndc no

#### Schering-Plough

Data tables

- schering chargeback 1991 1994
- schering\_chargeback\_1995\_1998
- schering chargeback 1999 2001
- schering\_chargeback\_2002\_2004

#### Drugs included

• Albuterol, Intron, Perphenazine, Proventil, Temodar

#### Time coverage

1991–2004

Fields for calculating dollar volumes and prices

- extended\_amount
- quantity

Fields for identifying relevant purchasing entities

- customer\_name
- buying group name
- customer state

Fields for identifying products

ndc\_no

## **Data processing**

- Create purchaser table
  - Identify relevant purchasing entities using customer name, owner name, and state fields present in the manufacturer data
    - Identify purchases by Massachusetts TPPs and their related entities<sup>21</sup>

<sup>21</sup> The following section details the entities I include in my analysis.

- For payors other than CIGNA, a national health plan, I restrict my analysis to purchases in Connecticut, New Hampshire, New Jersey, New York, Massachusetts, Rhode Island, and Vermont.
- Create sales table
  - Pull sales data from manufacturer chargeback tables as specified above.
    - · Limit selection to NDCs included in Dr. Hartman's damage analysis
- Merge sales table and purchaser table
  - Keep only sales data for relevant purchasing entities
- · Merge manufacturer data with Dr. Hartman's AWP and ASP data
- For table 2, sum purchases by Massachusetts TPP and manufacturer
- For table 3, sum purchases by Massachusetts TPP and year
- For price graphs, calculate quantity-weighted purchase prices by year and Massachusetts
   TPP

#### Relevant purchasing entities

(12) Table 4 below lists the customer/contracting entities appearing in the manufacturer chargeback data that I identify as being related to a Massachusetts TPP.